

## REMARKS

### Notice of Non-Compliant Amendment

The Supervisory Legal Instruments Examiner states in a Notice of Non-Compliant Amendment dated February 10, 2004, that the Amendment filed January 22, 2004 "omitted limitations that were previously added."

Upon review of claim 3, Applicants inadvertently omitted the underlined wording in the following recitation:

"an immunologic composition wherein said composition comprises an edible portion of a transgenic plant which expresses an antigenic determinate of said pathogen and wherein said administering is at a dosage level capable of generating protection against said pathogen in the absence of an antibody response".

The above recitation has been cancelled from claim 3. Applicants respectfully submit the claim as amended includes these limitations, therefore does not expand the scope of claim 3. Applicants respectfully request reconsideration.

### CLAIM REJECTIONS–35 USC §112

Claims 3, 29-34 are rejected under 35 USC §112, second paragraph for reasons of record advanced of the previous Office Action mailed May 7, 2003. The Examiner states:

The intended metes and bounds of the "determinate" region is not defined. Is expression of 12 nucleotide from a pathogen in a plant sufficient to induce protection? The intended pathogen is not defined. Is HIV intended? The intended transgenic plant is defined. Is cacti intended? In addition, the intended "eliciting protection" is not defined...[s]till further, the dosage level is not defined. In addition, claim 3 is rejected as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. The omitted elements are: viral pathogen, "antigenic determinate", plant type, "dosage level", etc.

*PTO Paper* dated October 14, 2003 at pp. 2-3.

Applicant has amended independent claim 3 to more clearly define the metes and bounds of the claim. Claim 3 has been amended to read on a method of eliciting protection against challenge from a pathogen causing disease in an animal without the animal developing serum level antibodies.

As amended claim 3 recites “preparing a vaccine material having edible plant portions of a transgenic maize plant which expresses an antigenic protein of a pathogen”, thus reciting a specific plant.

Applicant respectfully submits that a specific viral pathogen is not disclosed as being a “critical feature” as alleged by the Examiner. Starting on page 20 of the specification at line 24, Applicant discloses that the present invention may be used to produce any type of immunogenic composition effective in protecting humans and animals against diseases such as viruses, bacteria, fungi, and parasites. In view of the amendment made to claim 3, Applicant respectfully requests reconsideration and withdrawal of this rejection by the Examiner.

Applicants have amended claim 3 to recite “an amount of said vaccine material that is less than an amount sufficient to develop serum level antibodies against said pathogen”. Applicant respectfully submits that the dosage level does not need to be “defined” because according to the invention, methods of dosing and regulating antibody presence are known to those skilled in the art and a determination of the appropriate dose consistent with the teachings of the specification amounts to nothing more than routine optimization of parameters known and determined by those skilled in this art. Applicant respectfully requests that this rejection be withdrawn.

#### **CLAIM REJECTIONS-35 USC §102**

Claims 3, 30-33 are rejected to 35 USC §102(d) as being anticipated by Lam et al. (WO 94/20135), for reasons of record advance in the previous Office Action mailed May 7, 2003.

Applicant respectfully submits that under § 102, the prior art must disclose each and every limitation found in the claims, either expressly or inherently. *Rockwell Intern. Corp. v. US*, 147 F.3d 1358, 1363 (Fed. Cir. 1998); *Electro Med. Sys. S.A. v. Cooper Life Sciences*, 34 F.3d 1048, 1052 (Fed. Cir. 1994). Each claim limitation must be found in a single prior art reference; references cannot be combined under § 102. *Apple Computer, Inc. v. Articulate Systems, Inc.*, 234 F.3d 14, 20 (Fed. Cir. 2000). Omission of any claim element, no matter how insubstantial, is grounds for a traverse in a rejection based on § 102. *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542 (Fed. Cir. 1983).

Applicant respectfully submits that Lam fails to disclose a vaccine or composition which confers immunity in an animal to subsequent challenge with a pathogen without developing serum level antibodies to the pathogen expressed by the plant. On page 6, Lam discloses the preferred state of the composition of matter which is used to induce an immune response will depend upon the ability of the immunogen to elicit a mucosal response. The mucosal immunogen (or antigens) of Lam's invention are those mucosal antigens which prime the mucosal immune system and/or stimulate the humoral immune response, which results in the production of antibodies in the serum (see page 4, lines 10-11), in a dose-dependent manner. So, Lam in effect discloses observing an antibody response in serum.

This is in stark contrast to Applicant's invention as claimed, in which the Inventor has found that animals fed the vaccine material or immunogenic composition do not develop serum antibody levels. (See amended claim 3.). This is exemplified in Example 3. Table 1 and Table 2 at page 56 show the seroconversion of serum in the animals in both tests. As can be seen, those animals fed transgenic corn did not develop serum antibodies levels and were identical to the control corn group, except for showing protection. Lam fails to disclose the limitation that upon administering of an immunologic composition no serum level antibodies need be detected in

order to obtain protection from a pathogen upon subsequent challenge. Therefore, Lam does not anticipate Applicant's instantly claimed invention. Applicant respectfully requests that this rejection be withdrawn.

**CLAIM REJECTIONS-35 USC §112**

Claims 3, 29-33 were rejected under 35 USC §112, second paragraph as being indefinite for failing to particularly point out and distinctly claiming the subject matter which Applicant regards as the invention. The Examiner states:

Claim 3 is vague, indefinite and confusing for recitation of "dosage level capable of generating protection against said pathogen."

*Id.* at p. 6.

Applicant has amended claim 3 to recite orally administering "an amount of said vaccine material that is less than an amount sufficient to develop serum level antibodies against said pathogen", thereby reciting a level of vaccine that elicits protection against the pathogen without developing serum level antibodies to the pathogen.

Further, the Examiner states:

Claim 29 is indefinite for recitation for "TGEV". A full name followed by an acronym should be recited.

*Id.*

Applicant has amended claim 29 by reciting the full name of TGEV followed by the acronym, thus alleviating this rejection.

Additionally, the Examiner states:

Claim 34 recites the limitation "S protein" in line 1. There is insufficient antecedent basis for this limitation in the claim. In addition, what does this mean, the intended protein "S" is not defined.

*Id.*

Applicant has amended claim 34 to more clearly recite that the "S protein" means a large spike glycoprotein (S), which is a structural protein contained in TGEV virions. The amendments made to claim 3 provide sufficient antecedent basis for this limitation. Support is found on page 47, lines 23-31 to page 48, lines 1-2. Applicant respectfully requests this rejection be withdrawn.

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a response in the above identified application for 2 months from February 14, 2004 to March 14, 2004.

Applicant is a small entity under 37 CFR 1.9 and 1.27. A small entity statement under 37 CFR 1.27 has already been filed in this application.

Please charge Deposit Account No. 26-0084 in the amount of \$210.00 to cover the cost of the extension. Any deficiency or overpayment should be charged or credited to Deposit Account 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,



EDMUND J. SEASE, Reg. No. 24,741  
McKEE, VOORHEES & SEASE, P.L.C.  
801 Grand Avenue, Suite 3200  
Des Moines, Iowa 50309-2721  
Phone No: (515) 288-3667  
Fax No: (515) 288-1338  
**CUSTOMER NO: 22885**

Attorneys of Record

- HSN/pw -